

REMARKS/ARGUMENTS

The Pending Claims

Claims 1-26 and 35-46 are pending, which claims are directed to a composition for the inhibition of the translation of a Mect1-MAML2 chimeric gene.

Amendments to the Specification

The specification has been amended to recite the amino acid sequence of the Mect1-MAML2 chimera which was incorporated into the originally filed specification by reference to PCT/US02/021344 (e.g., original specification at paragraph 4). This amendment is in accordance with 37 CFR § 1.57 and introduces no new matter.

A Replacement or Amended Sequence Listing, which includes the amino acid sequence of the Mect1-MAML2 as SEQ ID NO: 12, is enclosed herewith.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. Specifically, claim 1 has been amended to point out more particularly and claim more distinctly the Mect1-MAML2 chimeric gene, as supported by paragraph 14. Claims 3, 4, 8, and 14 have been amended to further clarify the claim language. Claims 35-46 are new and supported by the original claims and the specification at, for example, paragraph 14. Claims 27-34 have been canceled as directed to non-elected subject matter. No new matter has been added by way of these amendments.

Summary of the Office Action

The Office acknowledges that claim 1 is a linking claim. Once the linking claim is found to be allowable, the restriction requirement as to the linked inventions will be withdrawn and the claims, depending from or otherwise including all the limitations of the allowable linking claims, will be entitled to examination.

The Office rejected claims 3 and 12-14 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office rejects claims 1-3, 6, 8-15, and 18-26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Office rejects claims 1, 4, 5, 8-11

and 18-24 under 35 U.S.C. § 103(a) as allegedly obvious in view of Wilda et al. (*Oncogene*, 21: 5716-5724 (2002)) in combination with Tonon et al. (*Nature Genetics*, 33: 208-213 (2003)), Sui et al. (*PNAS*, 99: 5515-5520 (2002)), Graham (U.S. Patent 6,573,099), Nicklin et al. (*Current Gene Therapy*, 2: 273-293 (2002)), Parrish et al. (*Molecular Cell*, 6: 1077-1087 (2000)), and Elbashir et al. (*EMBO J.* 20: 6877-6888 (2001)).

The Office objects to claims 6 and 16 as depending from a rejected base claim; however, the Office indicates that claims 6 and 16 would be allowable if rewritten in independent form.

Reconsideration of these rejections is hereby requested.

Summary of the Examiner Interview

Applicants thank Examiner Vivlemore for her discussion with Applicants' representative, John L. Gase, on January 17, 2006. The matters discussed are substantially as set forth herein.

Discussion of the Indefiniteness Rejection

The Office rejects claims 3 and 12-14 as allegedly indefinite for reciting that the chimeric gene and its complement are joined by a restriction enzyme sequence. The Office contends that restriction enzymes are recognized in the art to cleave DNA, not to join fragments.

Applicants believe that one of ordinary skill in the art would understand what is meant by "a restriction enzyme sequence" in the context of the claims and specification as originally filed. However, to advance prosecution, claims 3 and 12-14 have been amended to instead recite a nucleic acid sequence recognized by a restriction enzyme. The indefiniteness rejection is moot in view of the amendment and should be withdrawn.

Discussion of the Written Description Rejection

The Office rejects claims 1-3, 6, 8-15, and 18-26 as allegedly lacking written description because the claims allegedly encompass a broad genus of compounds comprising a fragment of *any* Mect1-MAML2 chimeric gene from *any* species.

Applicants disagree with the rejection. The specification describes a Mect1-MAML2 chimeric gene with a nucleic acid sequence of SEQ ID NO: 1, as well as homologues of the Mect1-MAML2 chimeric gene. The specification describes various homologues of the Mect1-MAML2 chimeric gene that share from as much as about 99% homology to as little as 10% homology. Given the description in the specification, one of ordinary skill in the art could envision the structure of the Mect1-MAML2 chimeric gene set forth in the claims.

However, to advance prosecution, the pending claims have been amended to recite a fragment of a nucleic acid that encodes the Mect1-MAML2 protein of SEQ ID NO: 12. Also, new claims have been added, which recite a fragment of a nucleic acid encoding a Mect1-MAML2 chimeric gene, wherein the nucleic acid sequence has about 90% or greater homology to nucleic acid sequence of SEQ ID NO: 1. The specification fully describes such chimeras at, for example, paragraph 14, as amended herein.

In view of the amendments, the written description rejection is moot and should be withdrawn.

Discussion of the Obviousness Rejections

The Office rejects claims 1, 4, 5, 18, 19, 23, and 24 as obvious in view of Wilda et al. in combination with Tonon et al. The Office relies upon several additional references (namely, Sui et al., Graham, Nicklin et al., Parrish et al., and Elbashir et al.) for the alleged recitation of certain elements of dependent claims.

Tonon et al. published online on January 21, 2003, which is less than one year before the filing date of the present application. Accordingly, Tonon et al. qualifies as prior art only if such reference were published “by another.” 35 U.S.C. § 102(a).

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132, executed by Dr. Frederic Kaye and Dr. Takefumi Komiya, stating that Tonon et al. describes the inventors’ own work. Accordingly, Tonon et al. is not prior art under 35 U.S.C. § 102(a) and cannot, therefore, be cited as a basis for rejection of the present application (*In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (C.C.P.A. 1982)).

Wilda et al. discloses only the inhibition of the BCR/ABL fusion gene through RNA interference. Neither Wilda et al. nor any other reference cited by the Office discloses the Mect1-MAML2 chimeric gene or compositions for inhibiting the Mect1-MAML2 chimeric gene.

As the remaining cited references do not disclose all elements of the claims, they do not render the claimed subject matter obvious. Accordingly, the Section 103 rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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